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Via email to:
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COMMENT LETTER

dshs.ems-trauma@dshs.Texas.gov
Texas Department of State Health Services
Texas Health and Human Services Commission

Re: Draft Rules, Hospital Level of Care Designations for Neonatal Care, Project No. 20R002

To Whom It May Concern::

On behalf of our more than 450 member hospitals and health systems, including rural, urban, children's, teaching and specialty hospitals, the Texas Hospital Association is pleased to comment on the draft rules for Hospital Level of Care Designations for Neonatal Care (Subchapter J, Chapter 133, Title 25 of the Texas Administrative Code). THA appreciates DSHS and HHSC's commitment to an open and transparent rulemaking process. THA member hospitals continue to evaluate the impact of the draft rules and THA will provide additional information as it becomes available.

Access to Peer Review Information - §§133,183(g)(5) and 133.184(v)

Section 133.183(g)(5) indicates that a facility "must provide the survey team access to records and documentation regarding the QAPI Plan and process to include peer review activities and minutes related to neonatal patients…" Section 133.184(v) indicates that at any time, "the department has the right to review, inspect, evaluate, and audit all neonatal patient records, neonatal multidisciplinary QAPI Plan documents, peer review activities, as well as any other documents relevant to neonatal care in a designated neonatal facility or facility seeking neonatal facility designation to verify compliance with the Texas Health and Safety Code, Chapter 241 and this section." The department is no doubt aware that medical peer review records are confidential by law and may only be disclosed as authorized by law. This general confidentiality standard is found at Texas Occupations Code section 160.007. That section allows disclosure of records of a medical peer review committee to, among others, an "appropriate state or federal agency. We do not find any explicit authority in Subchapter H of Health and Safety Code chapter 241 (the authorizing subchapter for neonatal level of care designations) for the department to access confidential peer review records in order to be considered by an appropriate state agency. We are even more concerned with a designated survey organization, and not the "state agency" itself, accessing confidential peer review records, as we do not find any authorization in either the Health and Safety Code or the Occupations Code for granting that access by rule.

We further question the need for either the agency or a survey organization to access peer review records, as we cannot envision any legitimate use of any information contained in peer review of an individual practitioner or

provider that would have any bearing on or relevance to whether the facility satisfies the level of care designation criteria.

We request that this new provision granting requiring access to peer review records be deleted from the rules.

Other Designation/Survey Process Issues – §§133.183(g) and 133.184

In addition to the issue noted above, with regard to the changes embodied in the draft revisions to §133.1844, we have the following comments:

- Survey Process Generally - §133.183(g): With regard to undergoing "an on-site or virtual survey", who determines and what criteria are used to determine whether a survey is virtual or on-site?
- Surveyor Conflict of Interest - §133.183(g)(4): With request to the statement "must not accept surveyors with any conflict of interest", we request that the language be modified to cover known or identified conflicts of interest, i.e., "must not accept any surveyors with any known conflict of interest", to avoid any suggestion that this is a strict liability standard if a facility was unaware of a conflict of interest at the time of the survey.
- Change of Ownership/Physical Location - §133.184(c): We note a change in ownership or physical location requires a facility to repeat the full designation process. We question why this would be necessary if there haven't been any programmatic changes as a result of a change in ownership or physical location. We request the language in this subsection pertaining to changes of ownership or physical location be removed.
- Display of designation certificate - §133.184(k)(1): This subsection requires that a designation certificate be physically displayed. We request that a facility alternatively be able to indicate its level of care designation on its website.
- Appeal Request by Chief Medical Officer - §133.184(q): We note that only the CEO or CNO may file an appeal of a designation determination. We request that Chief Medical Officer also be included in this list.
- Ongoing review/inspection/audit - §133.184(v): This subsection indicates that "[a]t any time, the department has the right to review, inspect, evaluate, and audit all neonatal patient records, neonatal multidisciplinary QAPI Plan documents, peer review activities, as well as any other documents relevant to neonatal care in a designated neonatal facility or facility seeking neonatal facility designation to verify compliance with the Texas Health and Safety Code, Chapter 241 and this section." This provision is not supported by Health and Safety Code section 241.185, which indicates that "[e]very three years, the executive commissioner and the department shall review the level of care designations assigned to each hospital and, as necessary, assign a hospital a different level of care designation or remove the hospital's level of care designation." The wording of this subsection in the draft rule suggests that the department could enter a facility at any time on a routine basis without any cause to believe that a facility is not in compliance with its level of care designation and request and receive unfettered access to the records of the facility merely to validate the continued validity of a level of care designation. We request that this language be eliminated or clarified to remove the possibility that a facility would be subjected to a revalidation survey at any time during its designation cycle.
- Plan of Correction (POC) Implementation – §133.184(a)(1)(C)(vi); - This subpart requires "documented evidence that the POC is implemented with data that demonstrates improvement within 60 days of the

designation survey." We do not believe that 60 days is enough time considering the surveying entity has 30 days to provide feedback to the facility, which then leaves only 30 days for the facility to demonstrate improvement of a finding with "data" to support. Further, an improvement implemented in this compressed timeframe likely does not demonstrate proficiency nor sustained improvement related to the finding. We request that this timeframe be extended to at least 120 days.

Neonatal Operations Committee Requirements - §133.182(24)

We note with some concern the new requirement to create a Neonatal Operations Committee and the myriad of functions the NOC performs. While some facilities may have the resources to operate a multidisciplinary committee with such a broad charge, smaller facilities will undoubtedly find the requirements extremely burdensome and excessively prescriptive within their neonatal operational plan. Moreover, even some larger facilities will find that implementing an Operations Committee as defined will inject unnecessary rigidity and complexity into their Operational Plan, require more administrative time from managerial and executive personnel, and take precious time away from patient care. We urge the department to maintain the flexibility for facilities, particularly Level I and Level II facilities, to determine within their Operational Plan how best to carry out the functions that are placed under the Operations Committee in the new provisions of the draft rule.

Waiver Criteria - §133.184(r)(2)(C)

This section permits the department to waive one specific designation requirement for a level of care designation if the department determines the waiver is justified considering, among other factors "(iii) whether these services can be met by other facilities" (emphasis added). Subsection (C) implements part of SB 749 from the 86th (2019) Legislative Session, specifically the enactment of Health and Safety Code section 241.1865. Section 241.1865(c) specifies the factors the department must consider when determining whether to grant a requested waiver and does not contain the quoted language. Therefore draft rule appears to contain factors for the department to consider that are in addition to the statutory language enacted by the legislature. We request that the quoted language be removed from §133.184(r)(2)(C)(iii).

Additionally, the way the factors are listed in §133.184(r)(2)(C)(i)-(iii) appear to require the department to find that a waiver is justified only after considering all of those factors whereas SB 749 as codified in Health and Safety Code section 241.1865 indicates that a waiver may be justified considering:

(1) the expected impact on:
  (A) the accessibility of care in the geographical area served by the hospital if the waiver is not granted; and
  (B) quality of care and patient safety; **or**
(2) whether health care services related to the requirement can be provided through telemedicine medical services under Section 241.1835 (emphasis added).

The rule should be written to reflect the wording of the statute that such that the factors set forth in (i) and (ii) are considered together and (iii) is an alternative factor that could justify granting a waiver request.

Quality Assessment and Performance Improvement Plan Requirements - §133.185(b)(3)

Oversight by CEO and CNO - §133.185(b)(3)(A)

The Chief Executive Officer and Chief Nursing Officer are required under this rule to "implement the culture of safety for the facility and ensure adequate resources are available to support a concurrent, data-driven QAPI Plan." We find the use of the subjective and undefined term "culture of safety" unusual for regulatory text and additionally believe this subpart is unnecessary. A facility either does or does not satisfy the designation criteria, and having a separate rule requiring specified individuals to ensure adequate resources adds nothing to the substantive requirements of the regulatory framework. We request that this subpart be deleted.

Neonatal Peer Review Committee Requirement – §133.185(b)(3)(D)

The draft rules specify a Level III and Level IV facility "must have a defined neonatal peer review committee with a defined and documented structure with required attendance as an element of their QAPI Plan." Since this is a new detail related to a facility's QAPI program, we are seeking clarification whether this is a requirement to establish a new committee specifically tailored to satisfying this element of the Level III and Level IV designation criteria versus utilizing an existing committee that is already part of a facility's perinatal services peer review structure to carry out this function. All neonatal hospitals have existing peer review committees established under existing medical staff structures. We are concerned that a requirement to establish a separate structure is unnecessary and overly prescriptive, *e.g.*, requiring the NMD to lead or co-lead the meeting, and operationally difficult to the extent it would require a facility to amend its medical staff bylaws to overhaul its peer review structure to comply with the rule.

Summary Reports for Telemedicine and Telehealth – §133.185(b)(3)(G)

With regard to the requirement that documented summary reports that reflect the monitoring and data analysis of patient outcomes and compliance to the telehealth/telemedicine policies and procedures are presented at the Neonatal Operations Committee: We believe there should be a distinction between telehealth services to address a medical need or behavioral need, and whether this provision requires tracking and reporting of psychologist and social worker visits with antepartum patients that are conducted via telehealth.

Availability of Medical and Surgical Subspecialists at Level IV Facilities - §§133.183(f)(4)(B), and 133.189(a)(2) and (d)(5)

Regarding the requirement in these subparts that a Level IV facility have a comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists to be immediately available to arrive on-site for in person consultation and care, we request that the department consider that this may be an overly prescriptive, one-size-fits-all approach to the availability of physicians who practice in specialties for which there is a known, chronic shortage and particularly for medical subspecialists who can provide the full range of services encompassed by their specialty without being on-site at the bedside.

Radiology Services - §§133.188(d)(11)(B) and (E), and 133.189(d)(10(B) and (E)

Regarding the requirements for a Level III facility that personnel appropriately trained in ultrasound, computed tomography, magnetic resonance imaging, and cranial ultrasound equipment must be on-site within 30 minutes of an urgent request, and that a radiologist with pediatric expertise must provide interpretation within 30 minutes of an urgent request: Rather than a firm response time that may not account for the circumstances that exist in each case, a better approach would be to adopt the same language as is contained in subpart (12), and require these services to be available within a time period consistent with current standards of professional practice.

We request the same change with respect to the requirements applicable to Level IV facilities in §133.189(d)(10(B) and (E).

Consultative Arrangements for Level I, II, and III Facilities - §§133.186(c)(4), 133.187(c)(4), and 133.188(d)(4)

These subsections require Level I-III facilities to "establish and maintain documented prearranged consultative agreements *with written standards of care and protocols for additional medical, surgical and support services*, which includes telehealth/telemedicine capabilities if used (emphasis added)." We believe it is unnecessary and impractical, and not in accordance with industry standards, for consulting arrangements to contain "written standards of care and protocols". Certainly, consultative arrangements generally set forth the minimum requirements and expectations of the arrangement, but do not typically set forth in the written agreement detailed standards of medical care and medical protocols. At most, the requirement should be that the consultant agree to abide by the Neonatal Plan, however, we urge the Department to remove this overly prescriptive language impacting the agreements a facility may enter into to carry out their Neonatal Plan.

Education and Outreach Requirements for Level III and Level IV Facilities - §§133.183(f)(3)(E) and (4)(E), 133.188(a)(5), and 133.189(a)(5)

We note that in draft changes to sections 133.183, 133.188, and 133.189, Level III and Level IV facilities are required to provide "outreach education to lower level neonatal designated facilities, non-designated facilities, birthing centers, independent midwife practices, and prehospital providers" (new requirements underlined). The change represents an expansion of responsibility placed on Level III and Level IV facilities, particularly in the category of prehospital providers if you consider that any physician or community clinic that provides prenatal care to be a prehospital provider. We are supportive of outreach education, but are concerned that in time of acute and chronic staffing shortages and dwindling resources, this requirement may place a burden on neonatal facilities they would find difficult to meet, and may require those facilities to dedicate new resources to areas that are not related to direct patient care. We ask that you revise the rule to encourage this expanded outreach but not mandating it in rule.

Other Provisions

Level IV Requirement for Availability of Pediatric Subspecialists - §133.189(d)(5) With respect to the requirement in this subpart that requires a "comprehensive range of pediatric medical subspecialists and pediatric surgical subspecialists must be immediately available to arrive on-site for in person consultation and care within 30 minutes of an urgent request": We request deletion of the word "immediately" since that is a defined term that

means "without delay or within 15 minutes" and therefore makes the definition confusing in light of the stated requirement in the provision requiring arrival within 30 minutes.

Evacuation Plan Testing - §133.185(b)(2)(F)

Regarding the requirement within the written operational plan related to a defined mother and infant evacuation plan and process to relocate mothers and infants to appropriate levels of care with identified resources, and that the process be "tested annually to ensure neonatal care can be sustained and adequate resources are available": We request clarification on what the specific testing requirements are.

We appreciate your consideration of these comments and for the opportunity to remain a part of DSHS's and HHSC's collaborative effort to ensure a regulatory scheme that protects patients, is operationally feasible, and provides clarity to those being regulated. Should you have any questions or need additional information, please do not hesitate to contact me at 512/465-1577 or swohleb@tha.org.

Respectfully submitted,

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