Texas Hospital Association

1108 Lavaca Street, Suite 700, Austin, Texas 78701
512/465-1000
www.tha.org

August 8, 2022

Via email to:
dshs.ems-trauma@dshs.Texas.gov

COMMENT LETTER

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

Re: Comments on Hospital Level of Care Designations for Maternal Care, Proposed Rule 21R143, Published July 8, 2022

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 proposed revisions to the rules for Hospital Level of Care Designations for Maternal Care (Subchapter K, Chapter 133, Title 25 of the Texas Administrative Code). THA appreciates DSHS and HHSC's commitment to an open and transparent rulemaking process and the opportunity that was afforded to review and comment on an earlier draft rules in February 2022, which we did. We note that some of the issues we identified were addressed in the proposed rules, but others were not. THA offers the following comments on the proposed revisions published on July 8, 2022
.

Placenta Accreta Spectrum Disorder and HB 1164 Requirements

As we previously indicated, we appreciate the work and the thoroughness that has gone into the rule revisions that implement the requirements of HB 1164 from the 87th (2021) Legislative Session related to placenta accreta spectrum disorder ("PASD"). We believe the rule revisions mostly embody the hard work and collaborative effort that went into HB 1164, but can be improved upon prior to adoption.

Clarification of privileges required of multidisciplinary team members - §133.203(f)(4)(F)

Under the General Requirements rule, a Level IV facility must have a placenta accreta spectrum disorder multidisciplinary care team "with the expertise and privileges to complete a risk factor assessment, screen, evaluate, diagnose, consult, and manage patients with anticipated or unanticipated placenta accreta spectrum disorder." It is not clear whether the reference to privileges means a clinical privilege delineation specifically related to PASD or merely refers to the privileges within a specialty that would allow the individual to manage these patients. Clarification is requested by adding "appropriate" before "privileges".

PASD Team Provisions - §133.209(d)(8)

As a general comment, the composition of the PASD Team as specified in the proposed rule is extremely specific and prescriptive. We believe a better approach would be to allow hospitals and health systems more flexibility to decide who and how best to care for these patients based on the providers' expertise in placenta accreta – not solely based on their specialty – and suggest that subsections (A) and (B) be eliminated. Additionally:

- In the opening paragraph of this subsection, we request that the words "to assume responsibility for" be deleted. This is not language common to regulatory text and does not add any meaningful substance or context to the rule. With this and the comment above taken together, the opening paragraph would thus read:

  (8) The facility shall have a Placenta Accreta Spectrum Disorder Team whose members have expertise ~~to assume responsibility for~~ in the diagnosis and management of pregnant or postpartum patients with anticipated and unanticipated placenta accreta spectrum disorder~~, including:~~.
- If the department is inclined to maintain the structure in the proposed rule, we request that the "surgeon or surgeons with expertise in pelvic, urologic, and gastroenterological surgery" be moved to the secondary team. The feedback we have received indicates that there is little value in having the required surgeon with expertise in pelvic, urologic, and gastroenterological surgery at the bedside, and a highly skilled OB or MFM with experience in these disorders should meet the requirement.
- With regard to subpart (E), which requires a board-certified maternal fetal medicine physician or an obstetrician/gynecologist with expertise in the diagnosis and management of placenta accreta spectrum disorder to lead the team, how is "expertise" defined, *i.e.*, is there specific training or a particular credential that the individual must have? Also, is the "lead" just a designation within the team, or are there survey criteria that will be applied to determine who is functionally leading the team?

Access to Peer Review Information - §§133,203(g)(5) and 133.204(v)

Section 133.203(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 maternal patients…" Section 133.204(v) indicates that at any time, "the department or surveyor has the right to review and evaluate maternal patient records, maternal multidisciplinary QAPI Plan documents, peer review documentation demonstrating why the case was referred, the date reviewed, pertinent discussion, and any action specific to improving maternal care and outcomes, as well as any other documents relevant to maternal care in a designated maternal facility or facility seeking maternal facility designation to validate designation requirements are met." 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 maternal 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. If the legislature intended for contractors, agents or designees of a state agency to have access to confidential peer review information, it would have granted that authority in statute. The

language in the proposed rule requiring a facility to grant access to surveyors to peer review information is not supported by the confidentiality provisions pertaining to peer review information and allowing access may constitute a breach of the statutory confidentiality protections afforded that highly sensitive information.

We further question the need for either the agency or a survey organization to access peer review records of individual practitioners, 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. Having the peer review process seems to be the important component, not the specific outcome of a peer review of individual practitioners.

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

Other Designation/Survey Process Issues – §133.204

In addition to the issue noted above, with regard to the changes embodied in the proposed revisions to §133.204, we have the following comments:

- Change of Ownership/Physical Location - §133.204(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 - §133.204(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.
- Plan of Correction Implementation – §133.204(a)(1)(D)(vi); - This subpart requires "documented evidence that the POC is implemented with data that demonstrates improvement within 90 days of the designation survey." We appreciate the change from 60 to 90 days from the draft rule to the proposed rule, but we remain concerned that even 90 days may not be enough time considering the surveying entity has 30 days to provide feedback to the facility, which then leaves only 60 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 again request that this timeframe be extended to at least 120 days.

Maternal Oversight Committee Requirements - §133.202(19)

We note with some concern the new requirement to create a Maternal Oversight Committee and the myriad of functions the MOC 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 maternal operational plan. We urge the department to maintain the flexibility for facilities, particularly Level I and Level II facilities, to determine within their Maternal

Program Plan how best to carry out the functions that are placed under the Oversight Committee in the new provisions of the proposed rule.

Level 1 Requirement for OB/GYN Physician Availability - §133.206(c)(3)

This subpart (in its proposed format) requires that "[a]n obstetrics and gynecology physician with obstetrics training and experience must be available at all times." We believe that the intent of this rule has always been that the OB/GYN physician be available at all times *for consultation*. We therefore request that the department take the opportunity to clarify the rule so that it reads as follows:

> (1) An obstetrics and gynecology physician with obstetrics training and experience must be available for consultation at all times.

Level III Criteria for Maternal Fetal Medicine Consultations - §133.208(d)(5)(C)

This subpart indicates that "[t]he use of telemedicine for on call consultation does not substitute for the requirement of maternal fetal medicine availability for in-person consultation on complex and critically ill patients on a regular basis." This language misstates the general requirement for the availability of an MFM physician at a Level III facility as set forth in §133.208(d)(5), which states (in its proposed format):

> (5) A board-certified or board-eligible Maternal Fetal Medicine physician with inpatient privileges must be available at all times for consultation and arrive at the patient bedside within 30 minutes of an urgent request to co-manage patients.

This general requirement states the specific circumstances under which in-person presence is required- to arrive within 30 minutes of an urgent request to co-manage patients. Nothing in the general requirement precludes telemedicine consultation for complex or critically ill patients on a regular or any other basis if there is no urgent request from the bedside physician to come to the facility. Despite this clearly articulated requirement, the new subpart (C) seems to impose a new and undefined standard that a hospital could not "regular[ly]" consult with its on-call MFM staff by phone or telemedicine. Many Level III facilities have gone to great lengths to ensure MFM coverage within the language of the existing rules and maintain a high level of care under these arrangements. New subpart (C) adds nothing to the designation criteria or the quality of services provided at Level III facilities other than a vague standard that will be applied subjectively by surveyors and will unnecessarily complicate the redesignation process. Accordingly, we request that new subpart (C) be removed.

Flexibility for Board Eligibility - §§133.207(c)(4), 133.208(d)(5) and (15)(C), 133.209(d)(3) and (14)(C)

We support the addition in the above-referenced sections/subsections to permit the utilization of board-eligible physicians instead of only board-certified physicians to satisfy certain designation criteria for Level II, III, and IV facilities. We believe this added flexibility is reasonable and will not compromise patient care or safety.

Waiver Criteria - §§133.204(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 the proposed 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 §133.204(r)(2)(C)(iii).

Additionally, the way the factors are listed in §133.204(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) of the proposed rule are considered together and (iii) is an alternative factor that could justify granting a waiver request. We suggest the revised subsection read as follows:

> (C) may waive one specific designation requirement for a level of care designation if the department determines the waiver is justified considering:
>
> (i) the expected impact on accessibility of maternal care in the geographic area served by the facility if the waiver is not granted and the expected impact on the quality of care and patient safety; or
>
> (ii) whether these services can be met by other facilities in the area or with telehealth/telemedicine services; and
>
> (iii) whether the facility met all other designation requirements for the level of care designation that are not waived in the agreement.

Quality Assessment and Performance Improvement Plan Requirements - §133.205(b)(3)

Oversight by CEO and CNO - §133.205(b)(3)(A)

The Chief Executive Officer, the Chief Medical Officer, and Chief Nursing Officer are required under this rule to "implement the culture of safety for the facility and ensure adequate resources to support a concurrent, data-

driven QAPI Plan are available." As we noted in our comments on the draft rule, 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 further believe the vague standards set forth in this subpart are ripe for controversy in an enforcement-type setting and do not believe that the text gives fair notice to the regulated parties of the standards to which they will be held. We request that this subpart be deleted.

Summary Reports for Telemedicine and Telehealth – §133.205(b)(3)(F)

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 Maternal Oversight 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. See also "General Comment" above.

Other Provisions

We have the following additional comment with regard to other provisions of the proposed rules not otherwise discussed herein:

- §133.205(b)(2)(G), regarding the requirement within the Maternal Program 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: We appreciate the change that the process be "evaluated annually" instead of "tested annually. The requirement to evaluate the process annually could be overly burdensome. We request that the requirement to evaluate the evacuation plan every three years to coincide with the re-designation cycle.
- Regarding §§133.208(d)(9) and 133.209(d)(9)(A) and (B) related to behavioral health services at Level III and Level IV facilities and the requirement that consultation by behavioral health professionals and psychiatrists, with experience in maternal or neonatal counseling be available for in-person visits when requested: given the chronic shortage of psychiatrists and other behavioral health professionals in Texas, the effectiveness of telemedicine and telehealth deliver we have seen during the COVID-19 pandemic, and in the age of improving telemedicine technology, telemedicine and telehealth should be a permissible option for this service if an in-person visit is not deemed necessary by the patient's physician.

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,

Stephen G. Wohleb
Senior Vice President and General Counsel
Texas Hospital Association