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

Dear Ms. Klein:

The 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 Maternal Rule Revisions Update. Texas Perinatal Services completed maternal surveys in 68% of the birthing hospitals across Texas in the first designation cycle. This experience provided our organization with a comprehensive knowledge of the processes in hospitals providing obstetrical care to Texans.

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

- Line 219: The directive for out-of-state surveyors in Level IV maternal 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. We understand the importance of addressing potential conflicts of interest, but we do not believe that this change will reliably and consistently exclude conflicts of interest.

The enhanced guidance provided to determine potential conflicts of interest is appreciated.

(h) If a conflict of interest is present for a facility seeking maternal designation, the facility must decline the assigned surveyor through the surveying organization. A conflict of interest exists when a surveyor has a current or past relationship with the facility or key facility staff members. The conflict of interest may include a previous working relationship, residency training, or participation in a consultation program, or designation survey for the facility within the past five years. Surveyors cannot be from the same PCR or TSA region or a contiguous region of the facility's location. Level IV facilities should have surveyors who currently practice outside of the state of Texas. If a survey occurs with a surveyor who has a defined conflict of interest, the maternal designation site survey summary will not be accepted by the department.

- Line 267: 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.

(C) if required by the department, a Plan of Correction (POC) that addresses all designation requirements defined as "not met" in the maternal designation site survey summary. The POC must include:

- (i) a statement of the cited designation requirement not met;
- (ii) a statement describing the corrective action taken by the facility seeking maternal designation to meet compliance with the requirement;
- (iii) the title of the individuals responsible for ensuring the corrective actions are implemented;
- (iv) the date the corrective actions are implemented;
- (v) how the corrective actions will be monitored; and
- (vi) documented evidence that the POC is implemented with data that demonstrates improvement within 60 days of the designation survey;

- Line 395: 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. I have reviewed the details in Senate Bill (SB) 749 but feel that additional clarification regarding how this will be addressed would be helpful, particularly considering the enhanced guidance regarding assessing for conflicts of interest within the survey team.

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

- Line 602: The requirement to stand up a separate maternal peer review committee is likely unnecessary and may be prohibitive for some facilities, dependent on their available resources. A requirement for specialized maternal representation on a hospital peer review committee would be sufficient.

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

- Line 893: The removal of the requirement for platelets to be maintained on-site at all times in Level II maternal facilities will likely assist with their ability to demonstrate compliance to the rule. However, the requirement for the facility's blood bank to be capable of implementing a massive transfusion protocol (MTP) remains in place. We agree with the requirement that the facility should have the capability to implement a MTP but are seeking clarification on reconciling the removal of platelets and continued requirement for MTP implementation capability.

(C) Laboratory and blood bank services shall be capable of:

- (i) providing ABO-Rh specific or O-Rh negative blood, fresh frozen plasma or cryoprecipitate, ~~and platelet products~~ on-site at all times;
- (ii) implementing a massive transfusion protocol;
- (iii) ensuring guidelines for emergency release of blood components; and
- (iv) managing multiple blood component therapy.

- Line 1295: The language in this section lacks clarity, as it lists a 30-minute timeframe and then notes a requirement for response “within a time frame commensurate to the clinical situation and consistent with current standards.”

(ii) arrive at the bedside within 30 minutes of an urgent request to attend to a patient with placenta accreta spectrum disorder within a time frame commensurate to the clinical situation and consistent with current standards;

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

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

Regards,



Dinah Welsh

President/CEO

TETAF/Texas Perinatal Services